



Clinical Trial Management Systems Breakout Session Summary Notes
caBIG Kickoff Meeting
February 19-20, 2004

This summary provides an overview of the key agreements in principle, discussion points, priorities and possible products for the Clinical Trial Management Systems Workspace - as discussed during the caBIG Kickoff Meeting breakout sessions. Further information on the Clinical Trial Management Systems Workspace activities will continue to be made available as the caBIG initiative moves forward. Please feel free to comment on these notes. If you are a registered caBIG participant and you have any comments or questions, please post them to the caBIG Forum at the following URL: <http://ncicbforums.nci.nih.gov/cabigforum>. If you are not a registered caBIG participant, please send any comments to adamsm@mail.nih.gov

The Clinical Trial Management Systems (CTMS) Workspace session participants agreed upon a set of requirements and principles for a standard CTMS software development approach. The key points of that discussion are provided below.

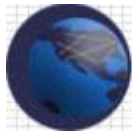
- caBIG Compatibility Requirements
 - caBIG General Principles
 - Apply open access, open source, open development, and federated approach to shared data and applications
 - Think of Workspaces as collaborative teams
 - caBIG Architectural Principles
 - Use uniform Application Programming Interfaces (APIs) and appropriate standard message formats to make data and analytic services available
 - Use common information models for biomedical data entities or objects to derive APIs and messages
 - Use common caBIG APIs to engineer applications
 - Use standards for data exchange formats
 - Document all systems, applications, and selected standards
 - caBIG Data Standards
 - Describe data using metadata elements that conform to accepted standards (e.g., ISO/IEC 11179)
 - Leverage metadata to achieve data interoperability and comparability
 - Construct and draw data and metadata from appropriate vocabulary and ontology standards
 - Use appropriate public, open access standards, where available
 - Engage in metadata development and curation activities relevant to participant's area of expertise
- CTMS Agreements in Principle for Componentized Development
 - Design Concept - Any tools built by the CTMS Workspace should be designed to work on multiple existing CDM Platforms
 - Componentized development is more efficient
 - Modular approach should support clinical trial life cycle phases
 - Focus on what is "doable" (choose something that's relatively simple, can have results sooner)



- Goal is to create applications for the whole community

CTMS participants identified a critical need for access to clinical trial data and emphasized the need for many tools and capabilities for varied data types and processes.

- Prioritized “Short List” of CTMS Modules/Tools
 1. Adverse Event Reporting
 2. Interfaces to Lab Systems
 3. CDUS/Theradex/CTEP Reporting
 4. Financial/Billing
- Action items (not prioritized):
 - Engage cooperative groups and industry sponsors (standard interfaces to eligible checklist and study calendar) in the process
 - Create an automated method for upload of laboratory values (interactions or bridges)
 - Sharing City of Hope – post AMIA paper (consider as a model – illustrates sharing of protocol information under a common framework)
 - Agree on a common framework or format for sharing information on studies for non-research (patient, public, etc.)
 - Establish a POC/Lead for each Center
 - Interface with HIPAA/Data Sharing and Intellectual Capital Working Group re: concerns/issues and best practices
 - Develop list of tools that Cancer Centers currently have and post them on the caBIG website
 - Put together a working group to develop a one-page lay summary template in a collaborative way
- CTMS Discussion Points
 - Consider disparate COTS/legacy systems in Working Group activities (some members have done detailed needs assessments)
 - Need to define common processes for functions, and allow for Center-specific differences
 - Use best practices in CTM planning and execution
 - Patient Identification feature in Oracle Clinical (link to Participant Registry); implemented in Oracle Clinical 4.5
 - Need to involve sponsors in standards/systems development process
 - Value of Protocol Management in caBIG
 - Ability to influence and implement regulatory compliance requirements
 - Future implementation support
 - Who should write the “user documentation” – Adopters or Developers
 - Bug tracking/Resolution – web-based portal for research community
 - Summary 4 reporting
 - Regulatory reporting
 - Support multiple destination formats for reporting
 - FDA, CTEP, IND, Holder, hospitals



- Need ability to extract and report data stored in CTMS, on both an ad hoc and scheduled basis
- Patient safety initiatives – possible future regulations
- CTMS Working Group - Specify adapters to make existing systems caBIG-compatible (work with Architecture and Vocabularies groups)
- NCICB – Provide details regarding Oracle Clinical business relationship (who can have it, what it includes, etc.) to group
- Additional Requirements for Consideration
 - Multiple Inputs
 - Web Interface
 - Database Access
 - Legacy data integration
 - Interoperability with multiple heterogeneous data sources
 - Middleware layer to facilitate interaction between components and data sources/targets, caBIG interface engine
 - Regulatory
 - Outcomes assessment
 - Automatic grading of toxicities for CTC (quantitative and qualitative)
 - Data conversion tools (transformation of data to common form)
 - Patient eligibility filtering/tracking
 - Matching patients to clinical trials
 - Systematic lay summaries
 - Investigator Registry



**Clinical Trial Management Systems Breakout Session Attendees
caBIG Kickoff Meeting
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Facilitator: Sue Dubman/NCICB

Cancer Center Name	Representative Name(s)
Case Western Reserve University – Ireland	Bob Lanese
City of Hope	Joyce Niland Doug Stahl
Duke University	Karen Johnson Pearl Seo
Fox Chase Center	Michael Bookman
Johns Hopkins University	Scott Finley
Karmanos Cancer Institute	Richard Rauscher
M.D. Anderson	Marcella Johnson
Mayo Clinic College of Medicine	John Carpenter
Memorial Sloan-Kettering	John Speakman
Northwestern University – Robert H. Lurie	Warren Kibbe
OHSU	Lara Fournier
University of California – San Francisco	Teri Melese
University of California – Irvine - Chao Family	Andrea Yicheng-hwang
University of Colorado	Jessica Bondy
University of Iowa – Holden	Jill Kuennen
University of Minnesota	Barry Brown
University of Nebraska – Eppley	Simon Sherman
University of Pennsylvania – Abramson	David Fenstermacher
University of Pittsburgh Medical Center	Michael Becich Douglas Fridsma William Gross Valerie Monaco
University of Wisconsin	Rhoda Arzoomanian
Vanderbilt University – Ingram	Sorena Nadaf
Wake Forest University	Robert Morrell
Washington University - Siteman	Brian Springer
Yale University	Cynthia Brandt
Private Industry Representatives	Name(s)
First Genetic Trust	Aris Floratos
Kevric	Christina Richardson
Patient Advocates	Name(s)
Cecchi Consulting	Donald J. Cecchi
International Waldenstroms Macroglobulinemia Foundation	Ben Rude
NCI Representatives	Name(s)

NCI	Christo Andonyadis/NCICB Smita Hastak/ScenPro Jean Jacques Maurer/Ekagra Beverly Meadows/CTEP Nancy Nelson/Press Office Anne Ryan/DCP Himanso Sahni/NCICB Gisele Sarosy/Office of Communications Felicia Solomon/CSD
caBIG Project Team Coordinators	Name(s)
Booz Allen Hamilton	Chalk Dawson Louise Goler-Brittain David Lyons Robin Portman

Workspace Working Group	Funded Members
Domain Workspace Working Group – Clinical Trial Management Systems	<ul style="list-style-type: none"> • University of California – San Francisco • Yale University • Northwestern University – Robert H. Lurie • University of Nebraska – Eppley • University of Iowa – Holden • University of Minnesota • University of Wisconsin • Vanderbilt University – Ingram <i>Plus representatives from each Developer and Adopter site</i>